

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicants: John D. Pruitt et al.

Title: SOLID DOSAGE FORMS COMPRISING PULLULAN

Appl. No.: 10/705,227

Filing Date: 11/12/2003

Examiner: Unassigned

Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop MISSING PARTS  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98, except as noted below.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 22, 2004

By Michele M. Simkin

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

Michele M. Simkin  
Attorney for Applicants  
Registration No. 34,717

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(as many sheets as necessary)

1 of 3

**Complete if Known**

Application Number	10/705,227
Filing Date	11/12/2003
First Named Inventor	John D. Pruitt
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	029318-0985

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,178,695		ERBEIA	12/18/1979	
	A2	4,616,047		LAFON	10/07/1986	
	A3	4,642,903		DAVIES	02/17/1987	
	A4	4,783,484		VIOLANTE ET AL.	11/08/1988	
	A5	4,826,689		VIOLANTO ET AL.	05/02/1989	
	A6	4,997,454		VIOLANTE ET AL.	03/05/1991	
	A7	5,073,374		MCCARTY	12/17/1991	
	A8	5,112,616		MCCARTY	05/12/1992	
	A9	5,145,684		LIVERSIDGE ET AL.	09/08/1992	
	A10	5,178,878		WEHLING ET AL.	01/12/1993	
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	A14	5,298,262		NA ET AL.	03/29/1994	
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	A18	5,328,404		BACON	07/12/1994	
	A19	5,336,507		NA ET AL.	08/09/1994	
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	A23	5,352,459		HOLLISTER ET AL.	10/04/1994	
	A24	5,384,124		COURTEILLE ET AL.	01/24/1995	
	A25	5,399,363		LIVERSIDGE ET AL.	03/21/1995	
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	A28	5,429,824		JUNE	07/04/1995	
	A29	5,446,464		FELDLE	08/29/1995	
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 Examiner  
Signature

 Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/705,227
				Filing Date	11/12/2003
				First Named Inventor	John D. Pruitt
				Group Art Unit	1615
				Examiner Name	Unassigned
Sheet	2	of	3	Attorney Docket Number	029318-0985

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		U.S. Patent Document			
	A42	5,518,902		OZAKI ET AL.	05/21/1996
	A43	5,521,218		OSIFO	05/28/1996
	A44	5,525,328		BACON ET AL.	06/11/1996
	A45	5,534,270		DE CASTRO	07/09/1996
	A46	5,543,133		SWANSON ET AL.	08/06/1996
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	A48	5,560,931		EICKHOFF ET AL.	10/01/1996
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Examiner Signature	Date Considered
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		U.S. Patent Document				
	A85	5,827,541		YARWOOD ET AL.	10/27/1998	
	A86	5,834,025		DE GARAVILLA ET AL.	11/10/1998	
	A87	5,851,553		MYERS ET AL.	12/22/1998	
	A88	5,862,999		CZEKAI ET AL.	01/26/1999	
	A89	5,866,163		MYERS ET AL.	02/02/1999	
	A90	5,869,098		MISRA ET AL.	02/09/1999	
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	A103	6,432,381	B1	LIVERSIDGE ET AL.	08/13/2002	
	A104	2002/0012675	A1	JAIN ET AL.	01/31/2002	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A105	WO	02/098565	A1	ELAN PHARMA INTERNATIONAL LIMITED	12/12/2002		
	A106	WO	98/14179	A1	CIMA LABS INC.	04/09/1998		
	A107	WO	98/46215	A1	CIMA LABS INC.	10/22/1998		
	A108	EP	0 636 365	A1	MCNEIL-PPC, INC.	02/01/1995		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A109	FDA/CFSAN: Agency Response Letter: GRAS Notice No. GRN 000099, August 1, 2002, <a href="http://vm.cfsan.fda.gov/~rdb/opa-g099.html">http://vm.cfsan.fda.gov/~rdb/opa-g099.html</a> , 5 pgs., obtained online 04/20/2004.	
	A110	Jakovljevi et al., "Fine Structural Analysis of the Fungal Polysaccharide Pullulan Elaborated by Aureobasidium pullulans, CH-1 Strain", <i>J. Serb. Chem. Soc.</i> , 66(6):377-383 (2001).	

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